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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,682	10/24/2001	Alan P. Wolffe	8325-0015.20	1541

20855 7590 06/21/2005

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/083,682	**Applicant(s)** WOLFFE ET AL.	
	Examiner Shubo (Joe) Zhou	**Art Unit** 1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

SAU

Continuation of 11:

The rejection of claims 66-71 and 125-128 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, applicants' argument is on the ground that the claims, disclosure and state of the art in Regents of the Univ. Calif. v. Eli Lily are entirely different from those in the instant application and thus does not apply to the instant case. This is not deemed persuasive. While it is true that the claims and disclosure in Regents of the Univ. Calif. v. Eli Lily are different from those in the instant application, it is in the same state of art: novel nucleic acids and/or polypeptides. Moreover, the fact patterns in both cases are similar in that they both claim nucleic acids and/or polypeptides whose sequences are not disclosed. Thus, the court decision in Regents of the Univ. Calif. v. Eli Lily applies to this case. The sequences of SEQ ID NOS: 10, 11 and 12 are not representatives of all the species of claimed genus. Applicants further argue that the claimed subject matter is not a single sequence encoding a known protein, but rather individual members of a library, whose sequences are impossible to disclose. This is not found persuasive because claims 66 and 125-128 are indeed drawn to a single polynucleotide. Without describing the structure including the sequence of the polynucleotide, the specification does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regard to the rejection of claims 66-71 and 125-128 under 35 U.S.C. 102(b) as being anticipated by Clontech (Clontech Catalog, 1998-1999, pages 177-183, Clontech Laboratories, Inc., Palo Alto, California), applicants' argument is on the ground that members of the Clontech libraries do not comprise an insert that consists essentially of accessible regions. This is not deemed persuasive because as set forth in the previous Office action, the phrase "consists essentially of " is interpreted as being open to unlisted ingredients. In this case, it is open to nucleotide from inaccessible region. As also set forth in the previous Office action, the Clontech libraries are made by a method involving digesting the whole genomes of the chromatin of different organisms with Sau3A I or Mbo I, which are four cutters and are known to digest the genomes with high frequency, and cloning the digested fragments in different vector systems. It would be readily apparent to one of skill in the art that the libraries produced by such a method inherently comprise clones that have an insert that either consists of polynucleotide from regions of cellular chromatin that are accessible to reagents such as nuclease and restriction enzymes, as recited in claims 125-128, and that such libraries should comprise clones with an insert that comprises polynucleotides from the accessible region and the inaccessible region. Applicants also argue that polynucleotides corresponding to inaccessible regions are not covered by the pending claims. However, the use of the phrase "consist essentially of" in the claims indicates that claims are open to such polynucleotides.

15 June 2005
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER